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10/759,215

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Bernard Querleux

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EXAMINER

CWERN, JONATHAN

ART UNIT

PAPER NUMBER

3737

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/759,215	<b>Applicant(s)</b> QUERLEUX ET AL.	
	<b>Examiner</b> Jonathan G. Cwern	<b>Art Unit</b> 3737	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/25/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Specification***

The abstract of the disclosure is objected to because it should not be written in the form of a claim, it should be written as a single paragraph without indents.

Correction is required. See MPEP § 608.01(b).

### ***Claim Objections***

Claims 1-34 are objected to because of the following informalities:

In claim 1 and 31, "the skin" lacks antecedent basis.

In claim 1, line 4, "the apparatus" lacks antecedent basis, it is only inferentially set forth in the preamble.

Claim 3 fails to impose any further structural limitations and merely defines a function of the coupling member.

It is unclear what further structural limitation has been set forth in claim 4.

In claims 16 and 17, "the entire analysis period" lacks antecedent basis.

In claim 20, there is no further structural limitation.

In claim 24, "the displacement of the vibrator".

In claim 26, "the step of processing" lacks antecedent basis.

In claim 32, "the effectiveness of treatment" lacks antecedent basis.

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1 and 8 state the device is in contact with the skin. As the skin is a part of the human body, a part of the body is being claimed, which is non-statutory subject matter.

Claims 25-30 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, lines 6-7 include functional language unsupported by structure to produce such a function. It is unclear how the probe is

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“arranged” to detect a displacement. It is unclear what the connection is between the vibrator and the probe. The use of the term “arranged” throughout the claims is confusing. It is unclear if the term “arranged” refers to a physical location of the element or a structural change or a software implemented element. In claims 13-15, the claims include functional language unsupported by structure to produce such functions, and it is unclear how the probe is “arranged” to function as set forth. The use of the term “arranged” throughout the claims is confusing. It is unclear if the term “arranged” refers to a physical location of the element or a structural change or a software implemented element. In claim 22, the phrase “all  $n$  time intervals  $dt$ ” is used. There appears to be a possible spelling/grammar error here. It is unclear what the value of  $n$  refers to, and what the value of  $dt$  refers to. Also,  $n$  lies in the range of 50 to 500 is unclear, it is unclear what 50 and 500 represent, and it is unclear what the associated unit is. In claims 32 and 33, it is unclear what is meant by the term “treatment that has action on a mechanical property of the skin”. In claim 34, it is unclear what “demonstrating activity” means, and the use of the word “revealed” is awkward. It is unclear how something is “revealed”.

Claim 25 provides for the use of the apparatus according to claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

It should be noted that the terminology in the claim, "by means of the apparatus according to claim 1" is interpreted as a use type of claim, that is, analyzing the skin using the apparatus of claim 1.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10-17, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Fink et al. (US 6770033).

Fink et al. disclose an imaging method and device using shearing waves. A vibrator is arranged against the skin of a patient, to generate shear waves into the viscoelastic medium. An ultrasound probe is used to observe the propagation of the shear wave. The probe can be arranged in a variety of ways, such as on the same side of the medium as the vibrator, on the opposite side, or any other position (column 4, line 66-column 5, line 67). The probe is arranged along an axis, and the vibrator is arranged in such a way that it can be considered "from a surface of the apparatus in contact with a region of the skin extending around the axis". As seen in Figure 1, the entire skin surface can be considered the "region of the skin", which extends around the ultrasound probe, and therefore the vibrator is in contact with a region of the skin extending around the axis. As seen in Figure 2, the vibrator, which is annular shaped, and probe can be

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arranged in such a way that the probe extends through a central bore in the vibrator.

The probe is arranged to emit and receive ultrasound waves in a frequency range of 1 to 100 MHz. The vibrator can emit a pulse with a frequency in the range of 20 to 5000 Hz.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al. (US 6770033) in view of Krause et al. (US 5545124).

Fink et al. disclose an imaging method and device using shearing waves. A vibrator is arranged against the skin of a patient, to generate shear waves into the viscoelastic medium. An ultrasound probe is used to observe the propagation of the shear wave. The probe can be arranged in a variety of ways, such as on the same side of the medium as the vibrator, on the opposite side, or any other position (column 4, line 66-column 5, line 67). The probe is arranged along an axis, and the vibrator is arranged in such a way that it can be considered "from a surface of the apparatus in contact with a region of the skin extending around the axis". As seen in Figure 1, the entire skin surface can be considered the "region of the skin", which extends around the ultrasound probe, and therefore the vibrator is in contact with a region of the skin extending around the axis. As seen in Figure 2, the vibrator, which is annular shaped, and probe can be arranged in such a way that the probe extends through a central bore in the vibrator. The probe is arranged to emit and receive ultrasound waves in a frequency range of 1 to 100 MHz. The vibrator can emit a pulse with a frequency in the range of 20 to 5000 Hz. Fink et al. fail to disclose a coupling member between the probe and skin.

Krause et al. disclose a method for alleviating the sensation of pain. As seen in Figure 1, an acoustic coupler in a disc shape can be disposed between the skin and the probe (column 5, line 64-column 6, line 7).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the probe of Fink et al. to use an acoustic coupler as taught by Krause et al. The use of an acoustic coupler in ultrasound systems is well known in the art. There are a variety of benefits provided by such a coupler, including



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establishing a stable connection between the skin and probe for ultrasound waves to propagate, or reducing the intensity of shockwaves. It would further be an obvious design choice to one of ordinary skill in the art, to select the size/thickness of the coupling member to be any size/thickness, which would enable the user to observe the desired portion of the patient's body via the focal length and depth. Furthermore, it would be an obvious design choice to modify the device of Fink et al. to incorporate the probe and vibrator into a frame. A frame, or housing, can allow for the parts of the device to be held in relation to each other, and to provide a level of support and protection for the components.

Claims 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al. (US 6770033) in view of Liu et al. (US 2004/0064050).

Fink et al. disclose an imaging method and device using shearing waves. A vibrator is arranged against the skin of a patient, to generate shear waves into the viscoelastic medium. An ultrasound probe is used to observe the propagation of the shear wave. The probe can be arranged in a variety of ways, such as on the same side of the medium as the vibrator, on the opposite side, or any other position (column 4, line 66-column 5, line 67). The probe is arranged along an axis, and the vibrator is arranged in such a way that it can be considered "from a surface of the apparatus in contact with a region of the skin extending around the axis". As seen in Figure 1, the entire skin surface can be considered the "region of the skin", which extends around the ultrasound probe, and therefore the vibrator is in contact with a region of the skin extending around

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the axis. As seen in Figure 2, the vibrator, which is annular shaped, and probe can be arranged in such a way that the probe extends through a central bore in the vibrator.

The probe is arranged to emit and receive ultrasound waves in a frequency range of 1 to 100 MHz. The vibrator can emit a pulse with a frequency in the range of 20 to 5000 Hz. Fink et al. fail to disclose analyzing the skin.

Liu et al. disclose a system and method for screening tissue. Liu et al. teach that the tissue can be skin. Different areas of the skin will yield different data, such as tissue mechanical properties, based on their state of healthiness. A tissue model can store information concerning for example, tissue elasticity, to compare with the obtained data. Data can also be acquired over time, and old data can be compared to new data to see if any changes in the skin have taken place over time ([0104]-[0106) and [0123]-[0126]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the system of Fink et al. to analyze the skin, as taught by Liu et al. While Fink et al. do not specifically state that the skin is analyzed using their device, one of ordinary skill in the art would recognize that such as device can be used to analyze a variety of different portions of the body, not only those discussed by Fink et al. It would be obvious to do so as any part of the body may require a diagnosis. While Liu et al. do not specifically mention determining the degree of aging of the skin, Liu et al. do compare values taken at different points in time, to determine if any changes have taken place in the skin. This can be considered an analysis of aging.

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Also, Fink et al. disclose that 1000 to 100,000 shots per second are fired by the ultrasound probe, and that the signals are sampled and digitized in real time after each shot. It would be an obvious design choice to one of ordinary skill in the art to select how often the probe stores/picks up the signals.

Claims 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al. (US 6770033) in view of Liu et al. (US 2004/0064050).

Fink et al. disclose an imaging method and device using shearing waves. A vibrator is arranged against the skin of a patient, to generate shear waves into the viscoelastic medium. An ultrasound probe is used to observe the propagation of the shear wave. The probe can be arranged in a variety of ways, such as on the same side of the medium as the vibrator, on the opposite side, or any other position (column 4, line 66-column 5, line 67). The probe is arranged along an axis, and the vibrator is arranged in such a way that it can be considered "from a surface of the apparatus in contact with a region of the skin extending around the axis". As seen in Figure 1, the entire skin surface can be considered the "region of the skin", which extends around the ultrasound probe, and therefore the vibrator is in contact with a region of the skin extending around the axis. As seen in Figure 2, the vibrator, which is annular shaped, and probe can be arranged in such a way that the probe extends through a central bore in the vibrator. The probe is arranged to emit and receive ultrasound waves in a frequency range of 1 to 100 MHz. The vibrator can emit a pulse with a frequency in the range of 20 to 5000 Hz. Fink et al. fail to disclose analyzing the skin.

Liu et al. disclose a system and method for screening tissue. Liu et al. teach that the tissue can be skin. Different areas of the skin will yield different data, such as tissue mechanical properties, based on their state of healthiness. A tissue model can store information concerning for example, tissue elasticity, to compare with the obtained data. Data can also be acquired over time, and old data can be compared to new data to see if any changes in the skin have taken place over time ([0104]-[0106) and [0123]-[0126]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the system of Fink et al. to analyze the skin, as taught by Liu et al. While Fink et al. do not specifically state that the skin is analyzed using their device, one of ordinary skill in the art would recognize that such as device can be used to analyze a variety of different portions of the body, not only those discussed by Fink et al. It would be obvious to do so as any part of the body may require a diagnosis. While Liu et al. do not specifically mention determining the degree of aging of the skin, Liu et al. do compare values taken at different points in time, to determine if any changes have taken place in the skin. This can be considered an analysis of aging. In any case, it would be an obvious to use the device to analyze a variety of different properties relating to the skin, depending on the user's preference.

Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al. (US 6770033) in view of Liu et al. (US 2004/0064050) and Popovic et al. (US 5115808).

Fink et al. disclose an imaging method and device using shearing waves. A vibrator is arranged against the skin of a patient, to generate shear waves into the viscoelastic medium. An ultrasound probe is used to observe the propagation of the shear wave. The probe can be arranged in a variety of ways, such as on the same side of the medium as the vibrator, on the opposite side, or any other position (column 4, line 66-column 5, line 67). The probe is arranged along an axis, and the vibrator is arranged in such a way that it can be considered "from a surface of the apparatus in contact with a region of the skin extending around the axis". As seen in Figure 1, the entire skin surface can be considered the "region of the skin", which extends around the ultrasound probe, and therefore the vibrator is in contact with a region of the skin extending around the axis. As seen in Figure 2, the vibrator, which is annular shaped, and probe can be arranged in such a way that the probe extends through a central bore in the vibrator. The probe is arranged to emit and receive ultrasound waves in a frequency range of 1 to 100 MHz. The vibrator can emit a pulse with a frequency in the range of 20 to 5000 Hz. Fink et al. fail to disclose analyzing the skin and using the data to determine the effects of a treatment.

Liu et al. disclose a system and method for screening tissue. Liu et al. teach that the tissue can be skin. Different areas of the skin will yield different data, such as tissue mechanical properties, based on their state of healthiness. A tissue model can store information concerning for example, tissue elasticity, to compare with the obtained data. Data can also be acquired over time, and old data can be compared to new data to see if any changes in the skin have taken place over time ([0104]-[0106) and [0123]-[0126]).

Popovic et al. disclose a method and device for noninvasive acoustic testing of elasticity of soft biological tissues. Popovic et al. teach that the elasticity of the skin can be measured before and after a treatment, to determine the effects of the treatment (column 7, lines 10-35).

It would have been obvious to one of ordinary skill in the art, to have used the system of Fink et al. in a variety of different ways, such as for analyzing skin as taught by Liu et al. The use of analysis methods for a variety of different reasons are well known in the art, such as diagnosis to determine which type of treatment, or what the most effective treatment will be. Or diagnosis to determine the effects of a treatment, to determine if the treatment is successful or if more treatment is necessary, or a different type of treatment. Popovic et al. provides several examples, such as analyzing the skin before and after a treatment to determine its effectiveness, diagnosing skin pathologies, or differentiating between normal and pathological tissue during surgical operations. It would be obvious to use the system of Fink et al. for any diagnosis purposes.

### ***Response to Arguments***

In view of applicant's Pre-Brief Conference request, prosecution has been reopened. The examiner finds the arguments filed 12/28/07 and in the appeal brief filed on 11/10/08 persuasive. As the Fink reference is again relied upon in the new rejections, the examiner responds below to the arguments filed on 7/24/07.

Applicant's arguments filed 7/24/07 have been fully considered but they are not persuasive. In regards to applicant's arguments regarding claim 1, examiner respectfully disagrees. Applicant's arguments are directed towards limitations which are NOT found in the claims. For example, applicant argues that Fink's vibrator does not extend around the probe. This limitation is not found in the claim. Also, that Fink's vibrator is not arranged to emit a shear wave from some other surface in contact with a region of skin extending around the probe. This limitation is not found in the claim. In addition, in regards to the argument regarding Figure 2 of Fink, the vibrator would indeed be in contact with that skin via some other component, that component being the probe.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., vibrator extending around the probe and vibrator arranged to emit a shear wave from some other surface in contact with a region of skin extending around the probe) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's arguments regarding claims 2 and 25 are persuasive.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is

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(571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/  
Examiner, Art Unit 3737

/Ruth S. Smith/  
Primary Examiner, Art Unit 3737